

## MINISTRY OF ENVIRONMENT AND FORESTS

### NOTIFICATION

New Delhi, the 20th September, 2006

**G.S.R. 616(E).**— Whereas the Ministry of Environment and Forests has notified the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, Rules 1989 hereinafter referred to as Rules vide No. GSR 1037 (E) dated 5<sup>th</sup> December 1989, --

And whereas rule 20 of the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, Rules 1989 empowers the Ministry of Environment and Forests to exempt an occupier handling a particular microorganism/genetically engineered organism from the application of the provisions of Rules 7 to 11 (both inclusive).

Now, therefore, in pursuance of rule 20 of the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, Rules 1989, the Central Government hereby considers it necessary that the manufacturer and/or importer of recombinant pharmaceuticals falling in the following categories may be exempted from the provisions of rules 7 to 10 (both inclusive) of the above said Rules with effect from the date of publication of this notification in the official gazette.

- (a) Indigenous product development, manufacture and marketing of pharmaceutical products derived from organisms falling under Risk Group I and Group II as specified in the Recombinant DNA Safety Guidelines, 1990.
- (b) Import and marketing of products derived from Living Modified Organisms (*LMOs*) as Drugs and Pharmaceuticals in bulk and/or finished formulations where the end product being imported is not a Living Modified Organisms.

[F.No. 12/7/2004-CS]

DESH DEEPAK VERMA, Jt. Secy.

**Note:—** the principal rules were published in the Gazette of India vide number GSR 1037 (E) dated 5.12.1989, which came into force vide notification SO 677 (E) DATED 13<sup>TH</sup> September 1993 and amended vide notification GSR 493 (E) Dated 14<sup>th</sup> July 2005.